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Michaela Hagermark

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EXAMINER

DEAK, LESLIE R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,963	Applicant(s) HAGERMARK ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,364,385 to Harms et al in view of US 4,396,382 to Goldhaber.

In the specification and figures, Harms discloses the apparatus substantially as claimed by Applicant. With regard to claims 1-5, Harms discloses a fluid bag 10 with a compartment that contains a fluid therein. The bag is made of flexible sheets, 11, 12 that are sealed along their periphery (see at least column 5, lines 30-40) and is configured to never exceed a certain thickness or depth when hung (see column 6, lines 61-68).

It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP § 2144.05(II)(A). It is the position of the Examiner that Harms discloses the general conditions of the claim (that is, a flexible-sheet fluid bag with a compartment wherein the bag is configured remain at a predetermined thickness when filled). As such, it is within the skill of a worker in the art to configure the bag to maintain a preferred volume-to-thickness ratio, since such a configuration may be obtained via routine experimentation.

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With regard to the contents of the bag, Harms discloses that the bag contains blood products, not dialysis fluids as claimed by Applicant. However, Goldhaber discloses a flexible bag that may contain fresh and spent dialysis fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the bag disclosed by Harms to contain the dialysis fluids as disclosed by Goldhaber, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claims 6-9 and 11-12, Harms discloses that the thickness or expansion of bag 10 is limited by a plurality of straight seal lines 60 (see column 6, lines 61-68).

With regard to claim 10, the prior art fails to disclose a looped distance limiting member. However, it has been held that matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art. See MPEP § 2144.04(I). In the instant case, it is the position of the Examiner that, absent persuasive evidence to show a significant result of the claimed shape, the shape of the weld is a matter of design choice that is not patentably distinct from the cited prior art.

With regard to claims 13-14, Goldhaber discloses that the bag comprises two compartments, allowing a single bag to be used for both fresh and spent dialysis fluid (see column 1, lines 35-40). Furthermore, it is the position of the Examiner that the mere duplication of the compartments found in the bag disclosed by Harms, without any

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new and unexpected results, is within the skill of a worker in the art. See MPEP § 2144.04 (VI)(B). As such, it is the position of the Examiner that the cited prior art suggests a multi-chambered fluid bag in order to simplify bag use with distance limiting members such as those taught by Harms in order to limit the thickness of the filled bag.

With regard to claims 15-16, Harms discloses an attachment member (hole 18 in edge 16) that allows the bag to be held in a suspended position (see FIG 1).

With regard to claims 17, 27, 28, and 38, Goldhaber discloses that the bag may be connected via conduit 34 to catheter 36 for peritoneal dialysis (see FIG 1 and accompanying text).

With regard to claims 18-19, 25, 29,30, Applicant is setting forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, both the Harms and Goldhaber bags are configured to be suspended by a holding apparatus via holes (see FIG 1 of each of Harms and Goldhaber). The prior art does not specifically cite the presence of a holding member, but reasonably suggests such a member, thereby suggesting the limitations of the claims (see, specifically, Harms, column 10-12, Goldhaber, column 5, lines 56-60).

With regard to claims 20-24, 26, 31, 35-37, it has been held that the mere duplication of the parts of an apparatus found in the prior art (such as the bags and holding means suggested in the combinations proposed above) is not patentably significant unless a new and unexpected result is produced. See MPEP § 2144.04

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(VI)(B). Furthermore, the placement of the bags as recited in claims 22-24 and 32-34 is a statement of the intended use of the claimed invention. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, it is the position of the Examiner that the bags suggested by the prior art are capable of being suspended in the arrangement claimed by Applicant, suggesting the limitations of the claims.

With regard to claim 39, the cited prior art suggests a bag with multiple compartments (Goldhaber) with distance limiting members (Harms) wherein the distance limiting members are formed at a location between the edges of the bag (Harms).

3. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2080116A to Matthews in view of US 4,396,382 to Goldhaber.

In the specification and figures, Matthews discloses the apparatus substantially as claimed by Applicant. With regard to claims 1-5, Matthews discloses a fluid bag with a compartment that contains a fluid therein. The bag is made of flexible sheets, 10, 12 that are sealed along their periphery (see specification) and is configured to never exceed a certain thickness or depth when hung.

It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

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experimentation. See MPEP § 2144.05(II)(A). It is the position of the Examiner that Matthews discloses the general conditions of the claim (that is, a flexible-sheet fluid bag with a compartment wherein the bag is configured remain at a predetermined thickness when filled). As such, it is within the skill of a worker in the art to configure the bag to maintain a preferred volume-to-thickness ratio, since such a configuration may be obtained via routine experimentation.

With regard to the contents of the bag, Matthews discloses that the bag contains waste products, not dialysis fluids as claimed by Applicant. However, Goldhaber discloses a flexible bag that may contain fresh and spent dialysis fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the bag disclosed by Matthews to contain the dialysis fluids as disclosed by Goldhaber, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claims 6-8, 10, and 11-12, Matthews discloses that the thickness or expansion of bag is limited by a plurality of looped welded members 20 (see FIG 1).

With regard to claims 13-14, Goldhaber discloses that the bag comprises two compartments, allowing a single bag to be used for both fresh and spent dialysis fluid (see column 1, lines 35-40). Furthermore, it is the position of the Examiner that the mere duplication of the compartments found in the bag disclosed by Matthews, without any new and unexpected results, is within the skill of a worker in the art. See MPEP § 2144.04 (VI)(B). As such, it is the position of the Examiner that the cited prior art

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suggests a multi-chambered fluid bag in order to simplify bag use with distance limiting members such as those taught by Matthews in order to limit the thickness of the filled bag.

With regard to claims 15-16, Goldhaber discloses an attachment member (unlabeled hole in top edge 18, see FIG 1) that allows the bag to be held in a suspended position.

With regard to claims 17, 27, 28, and 38, Goldhaber discloses that the bag may be connected via conduit 34 to catheter 36 for peritoneal dialysis (see FIG 1 and accompanying text).

With regard to claims 18-19, 25, 29, 30, Applicant is setting forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the Goldhaber bag is configured to be suspended by a holding apparatus via holes (see FIG 1 of Goldhaber). The prior art does not specifically cite the presence of a holding member, but reasonably suggests such a member (see, specifically, Goldhaber, column 5, lines 56-60).

With regard to claims 20-24, 26, 31, 35-37, it has been held that the mere duplication of the parts of an apparatus found in the prior art (such as the bags and holding means suggested in the combinations proposed above) is not patentably significant unless a new and unexpected result is produced. See MPEP § 2144.04 (VI)(B). Furthermore, the placement of the bags as recited in claims 22-24 and 32-34, is

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a statement of the intended use of the claimed invention. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, it is the position of the Examiner that the bags suggested by the prior art are capable of being suspended in the arrangement claimed by Applicant, suggesting the limitations of the claims.

With regard to claim 39, the cited prior art suggests a bag with multiple compartments (Goldhaber) with distance limiting members (Matthews) wherein the distance limiting members are formed at a location between the edges of the bag (Matthews).

Response to Arguments

4. Applicant's amendments to the drawings and claims render moot the drawing objections and 35 USC § 112 rejections presented in the non-final rejection.
5. Applicant's arguments filed 16 February 2010 have been fully considered but they are not persuasive.
6. Applicant argues that the volume to thickness ratio of the claimed bag, when in use, is not a recitation of the intended use of the device, but rather a structural limitation. The Examiner notes that the prior art teaches such structural limitations, thereby suggesting the limitations of the claims (see rejection above).

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7. Applicant argues that Harms teaches the use of a far smaller bag than that used by Applicant. The Examiner notes that the passage quoted by Applicant refers to *prior art* freezing bags. Harms specifically discloses that his invention is designed to provide a bag that can freeze and thaw blood products in a larger volume than that used in the past, specifically at least the volume of a conventional blood bag (see column 7, lines 15-35). As such, Harms does *not* teach away from the use of larger bags with expansion-limiting members.

8. Applicant argues that Goldhaber does not teach a bag with the claimed volume to thickness ratio. The Examiner notes that Goldhaber is not relied upon to teach those limitations—Goldhaber is relied upon to teach the use of a multi-compartment bag to store dialysis products.

9. Applicant argues that Matthews teaches away from a large-volume bag by emphasizing that the bag should remain relatively flat. However, such a disclosure does not teach away from larger-volume bags. Matthews discloses the use of thickness-limiting welds to reduce bulging, the number of which is variable depending on maximum desirable capacity (see column 1, lines 35-40). As such, Matthews does *not* teach away from the use of larger bags with expansion-limiting members.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
19 April 2010